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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,238	02/22/2006	Christopher John Montague Meade	1/1460 PCT	2614

28519 7590 09/25/2007

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/544,238	MEADE ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 29-36* is/are pending in the application.

4a) Of the above claim(s) *6-11 and 19-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,12-18,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Pursuant to the response filed 7/11/06, no claim has been added, amended or cancelled. Claims 1-25, 29-36 remain pending.

Claims 29-34 are withdrawn pursuant to the restriction; claims 6-11, 19-25 are withdrawn because they do not encompass the elected species. Claims 1-5, 12-18, 35, 36 are examined in this Office action.

✧

Claim 1 is objected to on grammatical grounds. The indefinite article ("a") should precede "pharmaceutical composition".

Each of claims 2-6, 12-17, 35, 36 is also objected to. The definite article ("the") should precede "pharmaceutical composition".

✧

Claims 1-5, 12-18, 35, 36 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 1, the term "TACE" may be used if accompanied by an explanation of what this abbreviation is intended to represent (presumably tumor necrosis factor-*alpha* converting enzyme).

- In claim 2, the phrase "the tiatropium salts" lacks antecedent basis.

- In claim 4, the cryptic terms "SL422", "SO057", "SC903" (etc.) may be used if accompanied by the chemical names (or structures) that these terms represent.

- Claim 12 asserts that a single composition is equal to two separate compositions, and that two separate compositions is equivalent to a single composition.

However, this is at odds with conventional notions of proper English grammar and usage. If deemed appropriate, applicants could add an independent claim which is drawn to two separate compositions.
In response to the foregoing, applicants have argued that it is possible to use the TACE inhibitor and the anticholinergic separately. This particular point is not in dispute. Applicants have then gone on to argue that when a drug formulation specialist of ordinary skill encounters the term "composition" in the singular, he immediately comes to the belief that this really refers to two separate compositions that are present in two separate containers. However, applicants are not correct.

- Claim 18 is drawn to an inhalable powder; this claim is asserted to be dependent on claim 17. Claim 17, by contrast, is drawn, not to an inhalable powder *per se*, but rather, to a pharmaceutical composition which is an inhalable powder. Accordingly, claim 18 should make reference to the pharmaceutical composition in the preamble, rather than the inhalable powder.

- In claim 35, the phrase "the tiatropium salts" lacks antecedent basis.

✧

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-5, 12-18, 35, 36 are rejected under 35 U.S.C. §103 as being unpatentable over Disse (US 2002/0193394) in view of Trifilieff, A. (*Br. J. Pharmacol.* **135**, 1655-1664, 2002).

Disse discloses that tiotropium is useful for treatment of COPD and asthma. Disse does not suggest combining tiotropium with a TACE inhibitor.

Trifilieff discloses that the TACE inhibitor PKF 242-484 [i.e., (2S,3R)-N-4-((S)-2,2-Dimethyl-1- methylcarbamoyl- propyl)-N-1-hydroxy-2-hydroxymethyl-3-(4- methoxy-phenyl)succinamide] is effective to treat COPD and asthma.

Thus, it would have been obvious to one of ordinary skill to combine the two agents for additive effects.

Applicants have argued that because the two references in question or no more related to one another than being in the "same field of endeavor", motivation to combine their teachings is lacking. However, to merely refer to the two references as being in the "same field of endeavor" is misleading. Presumably also, applicants would argue that if two people had been married and living together for 20 years, they would qualify as nothing more than acquaintances. Or that the pilot and co-pilot of an aircraft had nothing more in common than being just two people employed in the transportation sector. These characterizations would also be misleading. In the instant case, the two references disclose agents for treating the exact same disorder; the references are not just about the "same field of endeavor".

Next, applicants have argued in effect that if a patient takes two drugs in combination, each of which (when administered separately) is effective to treat the symptoms he is suffering from, the result is usually one of antagonism, i.e., according to applicants, two drugs in combination is usually less effective than either drug given alone. Thus applicants believe that if one were to take aspirin in combination with ibuprofen, the result would be less efficacy in the treatment of headache or fever than if either drug is given alone. And, according to applicants, a patient infected with HIV should never take an "AIDS cocktail" because two HIV replication inhibitors (in combination) are always less effective than one. Where applicants may have obtained such notions is far from clear, but applicants views do not reflect those of the pharmacologist of ordinary skill.

It is maintained that if a "first" reference discloses that a "first" agent is effective to treat a specific disease, and if, at the same time, a "second" reference discloses that a "second" agent is effective to treat the same disease as specified in the first reference, the pharmacologist of ordinary skill would expect, *a priori*, an additive effect, at least up to a saturation point. That is, whether a medical practitioner is administering one single drug, or two drugs in combination, or 20 drugs in combination, there will be a dosage above which no further benefit results. But below this "saturation point", one of ordinary skill would indeed expect additive effects.

The rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER